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12	UNITED STATES DIS	TRICT COURT
13	CENTRAL DISTRICT (OF CALIFORNIA
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15	FEDERAL TRADE COMMISSION,	
16	Plaintiff,	Case No. 8:18-cv-01838-AG-KES
17	v.	
18	REGENERATIVE MEDICAL GROUP,	ORDER ON STIPULATION FOR PERMANENT
19 20	INC., a corporation;	INJUNCTION AND
$\begin{bmatrix} 20 \\ 21 \end{bmatrix}$	TELEHEALTH MEDICAL CROUD INC	MONETARY JUDGMENT
$\begin{bmatrix} 21 \\ 22 \end{bmatrix}$	TELEHEALTH MEDICAL GROUP, INC., a corporation; and	
$\begin{bmatrix} 22 \\ 23 \end{bmatrix}$	•	
$\begin{vmatrix} 23 \\ 24 \end{vmatrix}$	BRYN JARALD HENDERSON, D.O.,	
$\begin{bmatrix} 2 & 1 \\ 25 & 1 \end{bmatrix}$	individually and as an officer of REGENERATIVE MEDICAL	
26	GROUP, INC. and TELEHEALTH	
27	MEDICAL GROUP, INC.,	
28	Defendants.	

Stipulated Order for Permanent Injunction and Monetary Judgment

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Plaintiff, the Federal Trade Commission ("Commission"), filed its Complaint for a permanent injunction and other equitable relief in this matter, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendants stipulate to the entry of this Stipulated Order for Permanent Injunction and Monetary Judgment ("Order"), to resolve all matters in dispute in this action.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

- 1. This Court has jurisdiction over this matter.
- The Complaint charges that Defendants participated in deceptive and unfair acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, in the advertising, marketing, and sale of stem cell therapy to treat, cure, and mitigate various diseases and health conditions.
- Defendants neither admit nor deny any of the allegations in the Complaint, 3. except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.
- 4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.
- Defendants and the Commission waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

- "Covered Product" means any Dietary Supplement, Food, Drug, or Device. 1.
- "Covered Service" means any health-related service, program, or therapy, 2.
- including the Stem Cell Therapy offered by the Regenerative Medical Group, Inc.,
 - TeleHealth Medical Group, Inc., and their successors and assigns.

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- 3. "**Defendants**" means the Individual Defendant and the Corporate Defendants, individually, collectively, or in any combination.
- A. "Corporate Defendants" means the Regenerative Medical Group, Inc., the TeleHealth Medical Group, Inc., and their successors and assigns.
 - B. "Individual Defendant" means Bryn Jarald Henderson, D.O.
- "Device" means an instrument, apparatus, implement, machine, contrivance, 4. implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or (3) intended to affect the structure or any function of the body of humans or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
- "Dietary Supplement" means (1) any product labeled as a dietary 5. supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.
- "**Drug**" means (1) articles recognized in the official United States 6. Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles

1	intended for use in the diagnosis, cure, mitigation, treatment, or prevention of		
2	disease in humans or other animals; (3) articles (other than food) intended to affect		
3	the structure or any function of the body of humans or other animals; and (4)		
4	articles intended for use as a component of any article specified in (1), (2), or (3)		
5	but does not include devices or their components, parts, or accessories.		
6	7. "Essentially Equivalent Product" means a product that contains the		
7	identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers,		
8	excipients) in the same form and dosage, and with the same route of administration		
9	(e.g., orally, sublingually), as the Covered Product; provided that the Covered		
10	Product may contain additional ingredients if reliable scientific evidence generally		
11	accepted by experts in the field indicates that the amount and combination of		
12	additional ingredients is unlikely to impede or inhibit the effectiveness of the		
13	ingredients in the Essentially Equivalent Product.		
14	8. "Food" means (1) any article used for food or drink for humans or other		
15	animals; (2) chewing gum; and (3) any article used for components of any such		
16	article.		
17	9. "Including" means including but not limited to.		
18	10. "Stem Cell Therapy" means any therapy that uses stem cells, including		
19	stem cells derived from amniotic fluid, amniotic membrane, adipose tissue, bone		
20	marrow, umbilical cord blood, and peripheral blood.		
21	ORDER		
22	Ι.		
23	PROHIBITED REPRESENTATIONS:		
24	HEALTH-RELATED CLAIMS REQUIRING		
25	HUMAN CLINICAL TESTING FOR SUBSTANTIATION		
26	IT IS ORDERED that Defendants, Defendants' officers, agents, and		
27	employees, and all other persons in active concert or participation with any of		
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them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Covered Service, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or service name, endorsement, depiction, or illustration, any representation that such product or service:

- A. Cures, mitigates, or treats any disease or health condition, including Parkinson's disease, autism, multiple sclerosis, cerebral palsy, traumatic brain injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis, and stroke; or
- Is comparable or superior to conventional medical treatments in В. curing, mitigating, or treating any disease or health condition; unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing of the Covered Product or Covered Service or, in the case of a food, drug, or dietary supplement, of the Covered Product or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent

and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II.

PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product or Covered Service, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or service name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Prohibited Representations: Health-Related Claims Requiring Human Clinical Testing for Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or Covered Service, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product or Covered Service or, in the case of a food, drug, or dietary supplement, of the Covered Product or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III.

FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits

Defendants, Defendants' officers, agents, and employees, or all other persons in active concert or participation with any of them from:

- A. For any drug, making a representation that is approved in labeling for such drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

IV.

PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Defendants rely to substantiate any claim covered by this Order, Defendants shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Defendant; (2) any Defendant's officers, agents,

representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Section, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendants, Defendants must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Defendants' size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

V.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

- A. Judgment in the amount of Three Million Three Hundred Ten Thousand Dollars (\$3,310,000) is entered in favor of the Commission against the Defendants, jointly and severally, as equitable monetary relief.
- B. Defendants are ordered to pay to the Commission Five Hundred Twenty Five Thousand Dollars (\$525,000) as follows:
- 1. One Hundred Seventy Five Thousand Dollars (\$175,000) within seven (7) days of entry of this Order;
 - 2. One Hundred Seventy Five Thousand Dollars (\$175,000)

within thirty (30) days of entry of this Order; and

- 3. One Hundred Seventy Five Thousand Dollars (\$175,000) within sixty (60) days of entry of this Order.
- C. Such payments must be made by electronic funds transfer in accordance with instructions previously provided by a representative of the Commission. Upon payment of the full Five Hundred Twenty Five Thousand Dollars (\$525,000) pursuant to Subsection B, the remainder of the judgment is suspended, subject to the Subsections below.
- D. In the event Defendants fail to pay Five Hundred Twenty Five Thousand Dollars (\$525,000) within sixty (60) days of entry of this Order, Defandants shall be in default and the full amount of the judgment shall immediately become due, plus interest from the date of entry of this judgment pursuant to 28 U.S.C. § 1961, less any payments already made. *Provided, however*, that in the event of default, the judgment amount set forth in Subsection A. above shall not become due if the Defendants cure such default within twenty one (21) calendar days.
- E. After the expiration of the time to cure the default, the Commission shall be entitled to immediately exercise any and all rights and remedies against the Defendants and their property to collect the full amount of the judgment amount set forth in Subsection A. above and interest thereon, less any payments already made.
- F. The Commission's agreement to the suspension of part of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendants' sworn financial statements and related documents (collectively, "financial attestations") submitted to the Commission, namely the:
- 1. Amended Financial Statement of Individual Defendant Bryn Jarald Henderson signed on July 24, 2018, including the attachments;
 - 2. Financial Statement of Corporate Defendant

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Regenerative Medical Group, Inc. signed by Bryn Jarald Henderson, CEO, on May 16, 2018, including the attachments; and

- 3. Financial Statement of Corporate Defendant TeleHealth Medical Group, Inc. signed by Bryn Jarald Henderson, CEO, on May 17, 2018, including the attachments.
- The suspension of the judgment will be lifted as to any Defendant if, upon motion by the Commission, the Court finds that Defendant failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial attestations identified above.
- If the suspension of the judgment is lifted, the judgment becomes Η. immediately due as to that Defendant in the amount specified in Subsection A. above (which the parties stipulate only for purposes of this Section represents the consumer injury alleged in the Complaint), less any payment previously made pursuant to this Section, plus interest computed from the date of entry of this Order.

VI.

ADDITIONAL MONETARY PROVISIONS

- Defendants relinquish dominion and all legal and equitable right, title, A. and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.
- B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.
- The facts alleged in the Complaint establish all elements necessary to C. sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral

estoppel effect for such purposes.

- D. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. §7701.
- E. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

VII.

CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly:

A. failing to provide sufficient customer information, in the form of full names, addresses, telephone numbers, email addresses, and amounts paid, to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to

- B. For 10 years after entry of this Order, Individual Defendant for any business that such Defendant, individually or collectively with any other Defendants, is the majority owner or controls directly or indirectly, and each Corporate Defendant, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.
- C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission:

- A. Sixty days after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:
- 1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendant must describe if he knows or should know due to his

own involvement); (d) describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

- 2. Additionally, Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.
- B. For 10 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
- 1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of any Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
- 2. Additionally, Individual Defendant must report any change in: (a) name, including aliases or fictitious names, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

- C. records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;
- D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and
 - E. a copy of each unique advertisement or other marketing material.

XII.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order, and any failure to transfer any assets as required by this Order:

- A. Within 14 days of receipt of a written request from a representative of the Commission, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.
- B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.
- C. The Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

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D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. §1681b(a)(1).

XIII.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED:

DATED: October 25, 2018

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United States District Judge Andrew J Guilford

ATTACHMENT A [On Regenerative Medical Group letterhead]

[on envelope]

IMPORTANT NOTICE ABOUT COURT SETTLEMENT

[content of letter, 16-point font]

Dear [Recipient]:

The Federal Trade Commission (FTC), the nation's consumer protection agency, has sued us for deceptive advertising related to our promises that our stem cell therapy treats a variety of serious diseases and health conditions. To settle the lawsuit we have agreed to:

- stop claiming that stem cell therapy treats or cures any disease or health condition, including Parkinson's disease, autism, multiple sclerosis (MS), cerebral palsy, traumatic brain injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis, and stroke; and
- stop claiming that stem cell therapy is comparable or superior to conventional medical treatments in curing, mitigating, or treating these diseases or health conditions.

The FTC says these claims are not currently backed by competent and reliable scientific evidence. Therefore, we can't make these claims in the future unless they can be supported by scientific proof.

You can find out more about the FTC's lawsuit at [URL].

Sincerely,

[Regenerative Medical Group signatory]

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Stipulated Order for Permanent Injunction and Monetary Judgment